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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,040	11/21/2006	Bin Wang	WANG0002-100	5612

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EXAMINER	
GANGLE, BRIAN J	

ART UNIT	PAPER NUMBER
1645	

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09/19/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,040	WANG ET AL.	
	Examiner	Art Unit	
	Brian J. Gangle	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 19-29* is/are pending in the application.

4a) Of the above claim(s) *22-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 19-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 August 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/22/2007, 7/16/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, claims 1-12 and 19-21, in the reply filed on 5/27/2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)) and is made FINAL.

Claims 1-12 and 19-29 are pending. Claims 22-29 are withdrawn as being drawn to nonelected inventions. Claims 1-12 and 19-21 are currently under examination.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. It is noted, however, that no English translation of the priority document has been made available.

Information Disclosure Statement

The information disclosure statements filed on 6/22/2007 and 7/16/2008 have been considered. Initialed copies are enclosed. Those documents that have been lined through were not considered because no copy of said documents has been provided.

Drawings

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the drawings submitted are blank. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Specification

This application fails to comply with the requirements of 37 C.F.R. 1.821-1.825 because it contains amino acid sequences that are not identified. For example, pages 6, 12, 13, 15, and 16 contain sequences that are not identified. Appropriate sequence identifiers should be used to comply with sequence rules. The sequences in the specification should match the sequence listing and computer readable form (CRF) submitted with the application. Applicant is asked to review the specification for sequences that are not identified and correction is required. Applicant must provide a substitute computer readable form (CRF) copy of the "Sequence Listing", a substitute paper copy of the "Sequence Listing", an amendment of the specification to insert appropriate sequence identifiers, and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

It is noted that the cited occurrences are only exemplary and applicant should review the specification to correct any other sequence issues.

The pages of the specification including claims and abstract must be numbered consecutively, starting with 1, the numbers being centrally located above or preferably, below, the text. The lines of the specification, and any amendments to the specification, must be 1 1/2 or double spaced. The spacing of the lines of the specification is such as to make reading difficult. New application papers with lines 1½ or double spaced on good quality paper are required. In addition, the numbering of the pages in the specification is incorrect. Multiple pages lack a page number.

The use of the trademarks TWEEN and PROGRAF have been noted in this application on pages 2, 9, and 17. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

It is noted that the cited occurrences of improper use are only exemplary and applicant should review the specification to correct any other use of trademarks.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6, 10-12, and 20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 10, and 11 of copending Application No. 11/644,435. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of copending Application No. 11/644,435 are drawn to a composition comprising a eukaryotic cell expression vector containing nucleotide sequences encoding an allergenic protein or a polypeptide that comprises an antigenic epitope of said allergenic protein and the protein or polypeptide that comprises an antigenic epitope of said protein. Said vector comprises an RSV, CMV, or SV40 promoter and the vector is in proportion to the protein in a ratio of 1:5 to 5:1.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 and 19-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-6 are rendered vague and indefinite by the phrase "a targeted nucleic acid vaccine." It is not clear how the nucleic acid vaccine is "targeted." Does this mean that the vaccine is somehow targeted to produce protein in a certain type of tissue (e.g., in tumor cells) or that it is meant to provide protection against a certain disease? It is also not clear how this "targeting" is supposed to occur. This rejection affects dependent claims.

Claims 1 and 5-6 are rendered vague and indefinite by the phrase "active polypeptide from a targeted antigen." It is not clear what an "active polypeptide from a targeted antigen" is. What activity is required for a polypeptide to be "active"? This rejection affects dependent claims.

Claims 1 are rendered vague and indefinite by the phrase "targeted pathogen nucleic acid vaccine." It is not clear how the nucleic acid vaccine is "targeted." Does this mean that the vaccine is somehow targeted to produce protein in a certain type of tissue (e.g., in tumor cells) or that it is meant to provide protection against a certain disease? It is also not clear how this "targeting" is supposed to occur. Finally, it is not clear how a "targeted pathogen nucleic acid vaccine" differs from a "targeted nucleic acid vaccine." This rejection affects dependent claims.

Claims 2, 5, and 7 are rendered vague and indefinite by the phrase "comprises a single package or a mixture." It is not clear how the inhibitor can be anything other than a mixture. If it is not a mixture or a "single package," what form is the inhibitor in? This rejection affects dependent claims.

Claim 3 is rendered vague and indefinite by the phrase "wherein the proportion of said targeted nucleic acid vaccine and said targeted antigen that is encoded by said nucleic acid vaccine is 2:1 to 10:1." Because the claim uses the proportion of A *and* B rather than A *to* B, it

is not clear what is in proportion to what. In addition, how are the components measured? Is it the mass, weight, volume, number of molecules, or some other unit that is in proportion?

Claim 4 is rendered vague and indefinite by the phrase "wherein the proportion of said targeted nucleic acid vaccine and said targeted antigen that is encoded by said nucleic acid vaccine is 5:1." Because the claim uses the proportion of A *and* B rather than A *to* B, it is not clear what is in proportion to what. In addition, how are the components measured? Is it the mass, weight, volume, number of molecules, or some other unit that is in proportion?

Claim 6 is rendered vague and indefinite by the phrase "wherein the proportion of said targeted nucleic acid vaccine and said active polypeptide from a targeted antigen that is encoded by said nucleic acid vaccine is 1:5 to 5:1." Because the claim uses the proportion of A *and* B rather than A *to* B, it is not clear what is in proportion to what. In addition, how are the components measured? Is it the mass, weight, volume, number of molecules, or some other unit that is in proportion?

Claim 8 is rendered vague and indefinite by the phrase "wherein the proportion of the inactivated targeted pathogen and the targeted pathogen nucleic acid vaccine is 1:2 to 1:10." Because the claim uses the proportion of A *and* B rather than A *to* B, it is not clear what is in proportion to what. In addition, how are the components measured? Is it the mass, weight, volume, number of molecules, or some other unit that is in proportion?

Claim 10 recites the limitation "said nucleic acid vaccine" in line 2. There is insufficient antecedent basis for this limitation in the claim. It is not clear whether "said nucleic acid vaccine" is the "targeted nucleic acid vaccine" or the "targeted pathogen nucleic acid vaccine."

Claim 12 is rendered vague and indefinite by the phrase "wherein said eukaryote cell expression vector is a plasmid, virus, bacteriophage." As a bacteriophage is a virus that infects bacteria, it is not clear how a bacteriophage can be a eukaryote cell expression vector. A bacteriophage might contain a eukaryotic expression vector, but it could not be one.

Claim 20 recites the limitation "said nucleic acid vaccine." There is insufficient antecedent basis for this limitation in the claim. It is not clear whether "said nucleic acid vaccine" is the "targeted nucleic acid vaccine" or the "targeted pathogen nucleic acid vaccine."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 5, 9-12, and 20-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Wen *et al.* (US Patent 6,221,664, 4/2001).

The instant claims are drawn to T-cell immune response inhibitors that comprise a targeted nucleic acid vaccine and a targeted antigen that is encoded by said nucleic acid vaccine; a targeted nucleic acid vaccine and an active polypeptide from a targeted antigen that is encoded by said nucleic acid vaccine; or a targeted pathogen nucleic acid vaccine and an inactivated targeted pathogen. Dependent claims include said inhibitor wherein an adjuvant is included and wherein the nucleic acid vaccine is a eukaryote cell expression vector with a RXV, CMV, or SV40 promoter.

Wen *et al.* disclose a vaccine comprising hepatitis B surface antigen as well as plasmid DNA which encodes said antigen and an adjuvant (see column 5, lines 1-26). The plasmid contains a CMV promoter (column 3, line 14).

Claims 1-2, 5, 7, 9-12, and 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Pundi *et al.* (WO 02/078732 A1, 10/2002).

The instant claims are drawn to T-cell immune response inhibitors that comprise a targeted nucleic acid vaccine and a targeted antigen that is encoded by said nucleic acid vaccine; a targeted nucleic acid vaccine and an active polypeptide from a targeted antigen that is encoded by said nucleic acid vaccine; or a targeted pathogen nucleic acid vaccine and an inactivated targeted pathogen. Dependent claims include said inhibitor wherein an adjuvant is included and wherein the nucleic acid vaccine is a eukaryote cell expression vector with a RXV, CMV, or SV40 promoter.

Pundi *et al.* disclose a vaccine formulation comprising a DNA vaccine that encodes a polypeptide of a virus as well as the inactivated virus (see abstract). The DNA vaccine includes a CMV promoter and the composition can also include an adjuvant (see pages 7-8).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 9-12, and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wen *et al.* (US Patent 6,221,664, 4/2001).

The instant claims are drawn to T-cell immune response inhibitors that comprise a targeted nucleic acid vaccine and a targeted antigen that is encoded by said nucleic acid vaccine; a targeted nucleic acid vaccine and an active polypeptide from a targeted antigen that is encoded by said nucleic acid vaccine; or a targeted pathogen nucleic acid vaccine and an inactivated targeted pathogen. Dependent claims include said inhibitor wherein an adjuvant is included and wherein the nucleic acid vaccine is a eukaryote cell expression vector with a RXV, CMV, or SV40 promoter. Dependent claims also include the inhibitor where the proportion of the nucleic acid vaccine and the targeted antigen is 2:1 to 10:1, or is 5:1, or the proportion of the nucleic acid vaccine and the active polypeptide from the targeted antigen is 1:5 to 5:1.

Wen *et al.* disclose a vaccine comprising hepatitis B surface antigen as well as plasmid DNA which encodes said antigen and an adjuvant (see column 5, lines 1-26). The plasmid contains a CMV promoter (column 3, line 14).

Wen *et al.* differs from the instant invention in that specific proportions are not disclosed.

However, it would have been obvious to one of ordinary skill in the art, at the time of invention, to choose any of the claimed proportions because differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. There is no

evidence in the instant specification to this effect and the breadth of the claims indicates that the proportion is not critical.

Claims 1-12 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pundi *et al.* (WO 02/078732 A1, 10/2002).

The instant claims are drawn to T-cell immune response inhibitors that comprise a targeted nucleic acid vaccine and a targeted antigen that is encoded by said nucleic acid vaccine; a targeted nucleic acid vaccine and an active polypeptide from a targeted antigen that is encoded by said nucleic acid vaccine; or a targeted pathogen nucleic acid vaccine and an inactivated targeted pathogen. Dependent claims include said inhibitor wherein an adjuvant is included and wherein the nucleic acid vaccine is a eukaryote cell expression vector with a RXV, CMV, or SV40 promoter. Dependent claims also include the inhibitor where the proportion of the nucleic acid vaccine and the targeted antigen is 2:1 to 10:1, or is 5:1, the proportion of the nucleic acid vaccine and the active polypeptide from the targeted antigen is 1:5 to 5:1, or the proportion of the inactivated targeted pathogen and the targeted pathogen nucleic acid vaccine is 1:2 to 1:10.

Pundi *et al.* disclose a vaccine formulation comprising a DNA vaccine that encodes a polypeptide of a virus as well as the inactivated virus (see abstract). The DNA vaccine includes a CMV promoter and the composition can also include an adjuvant (see pages 7-8).

Pundi *et al.* differs from the instant invention in that specific proportions are not disclosed.

However, it would have been obvious to one of ordinary skill in the art, at the time of invention, to choose any of the claimed proportions because differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. There is no evidence in the instant specification to this effect and the breadth of the claims indicates that the proportion is not critical. Furthermore, Pundi *et al.* state that the quantity of inactivated virus in the vaccine can vary widely depending on the immunogenicity and potency of the formulation (see page 5, lines 27-31).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Gangle whose telephone number is (571)272-1181. The examiner can normally be reached on M-F 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian J Gangle/
Examiner, Art Unit 1645

/Robert B Mondesi/
Supervisory Patent Examiner,
Art Unit 1645